K003676

8.0 510(K) SUMMARY OF SAFETY AND EFFECTIVENESS

General Provisions	Trade Name: RITA® Model 2500 Electrosurgical RF Generator Common/Classification Name: Electrosurgical cutting and coagulation device
Name of Predicate	RITA Medical Systems Inc. – Model 1500 and Model 500 Electrosurgical RF Generators
Classification	Class II
Performance Standards	Performance standards have not been established by the FDA under section 514 of the Food, Drug and Cosmetic Act.
Intended Use	The Model 2500 Electrosurgical RF Generator and accessories are indicated for use in percutaneous, laparoscopic, and intraoperative coagulation and ablation of soft tissue, including the partial or complete ablation of non-resectable liver lesions.
Device Description	The Model 2500 Electrosurgical RF Generator is designed to provide monopolar radiofrequency (RF) energy. The RF Generator is a 250 W electrosurgical generator specifically designed for use with RITA electrosurgical devices. It can read multiple temperature sensors and includes impedance and power monitoring to assist the physician in monitoring and controlling the ablation. To use the system, the RF Generator is plugged into the wall outlet via the Power Cord. The electrosurgical device is connected to the RF Generator via the Main Cable. The Dispersive Electrode is place on the appropriate location of the body and is connected to its port on the RF Generator. Once the system is successfully powered up, the user can set the parameters of the ablation such as the mode of operation, the ablation time, the target temperature, and the power delivery level. With the electrosurgical device placed in the tissue to be ablated and its electrodes deployed, RF power can be turned on. The system parameters are continuously monitored and displayed on the RF Generator. If the measured parameters are outside the acceptable limits, the RF energy delivery automatically stops and a message appears on the liquid crystal display (LCD). The RF energy delivery also automatically ceases once the ablation is completed based on the initial user-defined parameters. RF energy can be stopped at any time by pressing the RF ON/OFF switch.
Performance Data	The Model 2500 RF Generator was subjected to component testing and software validation testing.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR - 9 2001

Ms. Erin Mazzone
Director, Regulatory Affairs
Rita Medical Systems, Inc.
967 North Shoreline Boulevard
Mountain View, California 94043

Re: K003676
Trade/Device Name: Model 2500 Electrosurgical RF Generator
Regulation Number: 878.4400
Regulatory Class: II
Product Code: GEI
Dated: March 15, 2001
Received: March 19, 2001

Dear Ms. Mazzone:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Miriam C. Provost

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

3.0 INTENDED USE

Indications for Use Statement

510(K) Number (if known) K003676

Device Name: Model 2500 Electrosurgical RF Generator

The Model 2500 Electrosurgical RF Generator and accessories are indicated for use in percutaneous, laparoscopic, and intraoperative coagulation and ablation of soft tissue, including the partial or complete ablation of non-resectable liver lesions.

Miriam C. Provost
(Division Sign-Off)
Division of General, Restorative and Neurological Devices

510(k) Number K003676

PLEASE DO NO WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over the Counter Use _____
(per 21 CFR 801.109)